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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,660	10/24/2003	Mark E. Anderson	MEA-0201-C2	9636
35830 7590 01/04/2007 LAWRENCE N. GINSBERG 21 SAN ANTONIO NEWPORT BEACH, CA 92660-9112			EXAMINER PRICE, RICHARD THOMAS JR	
			ART UNIT	PAPER NUMBER
			3643	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
31 DAYS		01/04/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/693,660

Applicant(s)

ANDERSON ET AL.

Examiner

Thomas Price

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09-28-2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, 15-23 and 34 are, drawn to a method of creating a pathway in a tract of a mammal, classified in class 119, subclass 174.
- II. Claims 8-14, 24-33 and 35 are, drawn to a catheter, classified in class 119, subclass 174.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process can be performed by a conventional endoscope.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter and divergent electronic search queries needed to properly search each claimed invention, restriction for examination purposes as indicated is proper.

If the Applicant elects Group I, then the following election of species requirement is applicable.

This application contains claims directed to the following patentably distinct species:

Species IA is directed to a method of creating a pathway including inserting the tube in a mammal and extending the membrane from an opening in the tube, claims 1-7.

Species IB is directed to a method of creating a pathway including inserting the tube in a mammal, extending the membrane from an opening in the tube, and introducing fluidic material into said tube, claims 15-23.

Species IC is directed to a method of creating a pathway in a tract of an animal including inserting the tube in an animal, extending the membrane from an opening in the tube, and introducing fluidic material into said tube, claim 34.

The species are independent or distinct because the independent claims set forth alternative ways to create a pathway in the tract of a living organisms.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, there are no claims which are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

If the Applicant elects Group II, then the following election of species requirement is applicable.

This application contains claims directed to the following patentably distinct species:

Species IIA is directed to a catheter including a tube and a membrane initially positioned inside the tube, claims 8-14.

Species IIB is directed to a catheter including a tube, a membrane initially positioned inside the tube, and the fluidic material is introduced into said tube.

Species IIC is directed to a catheter including a tube configured to be inserted into a tract of a animal, a membrane initially positioned inside the tube and the fluidic material introduced into said tube.

The species are independent or distinct because the independent claims set forth alternative ways to create a pathway in the tract of a living organisms.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, there are no claims which are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

If the Applicant elects Group IA, then the following restriction requirement is applicable.

- IA-1. Claims 1 and 2 are drawn to the extension of the membrane is caused by pressure.
- IA-2. Claims 1, 3, 4 and 7 are drawn to depositing genetic material into the mammal.
- IA-3. Claims 1 and 5 are drawn to the tube having a tapered nozzle located at the opening of the tube.
- IA-4. Claims 1 and 6 are drawn to a tapered membrane.

Inventions IA-1—IA-3 and IA-4 are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination IA-4 has separate utility such as irrigating a fistula/abscess in the body of a mammal by introducing saline through the tube and membrane. See MPEP § 806.05(d).

If the Applicant elects Group IB, then the following restriction requirement is applicable.

IB-1. Claims 15, 16 and 20 are drawn to inserting the catheter in the reproductive tract.

IB-2. Claims 15 and 17 are drawn to inserting the catheter in the respiratory tract.

IB-3. Claims 15 and 18 are drawn to inserting the catheter in the circulatory tract.

IB-4. Claims 15 and 19 are drawn to inserting the catheter in the digestive tract.

IB-5. Claim 15 and 21-23 are introducing fluidic material into the tube.

Inventions IB-1—IB-4 and IB-5 are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination IA-5 has separate utility such as irrigating a fistula/abscess in the body of a mammal by introducing saline through the tube and membrane. See MPEP § 806.05(d).

If the Applicant elects Group IIA, then the following restriction requirement is applicable.

IIA-1. Claims 8 and 9 are drawn to the extension of the membrane is caused by pressure.

IIA-2. Claims 8, 10, 11 and 14 are drawn to a membrane configured to deposit genetic material into the mammal.

IIA-3. Claims 8 and 12 are drawn to a tube that has a tapered nozzle located at the opening of the tube.

IIA-4. Claims 8 and 14 are drawn to a membrane is tapered.

Inventions IIA-1—IIA-3 and IIA-4 are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination IIA-4 has separate utility such as irrigating a fistula/abscess in the body of a mammal by introducing saline through the tube and membrane. See MPEP § 806.05(d).

If the Applicant elects Group IIB, then the following restriction requirement is applicable.

IIB-1. Claims 24, 25, 29 and 30 are drawn to the tube being configured to be inserted in a reproductive tract.

IIB-2. Claims 24 and 26 are drawn to the tube being configured to be inserted in a respiratory tract.

IIB-3. Claims 24 and 27 are drawn to the tube being configured to be inserted in a circulatory tract.

IIB-4. Claims 24 and 28 are drawn to the tube being configured to be inserted in a digestive tract.

IIB-5. Claims 24 and 31 are drawn to the tube and membrane being configured so that the membranes unfolds.

IIB-6. Claims 24 and 32 are drawn to the tube and membrane being configured so that fluidic material is released through said opening.

IIB-7. Claims 24 and 33 are drawn to the membrane being formed of latex.

The examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter and divergent electronic search queries needed to perform a proper search, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

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distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas Price whose telephone number is 571-272-6892. The examiner can normally be reached on M-F from 6:30a.m. to 3:00p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Poon can be reached on 571-272-6891. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Thomas Price

Primary Examiner GAU: 3643

December 22, 2006

rtp